

CLAIMS

1. Pharmaceutical composition which can be administered orally, allowing the controlled release of at least one active substance comprising
 - a) the said at least one active substance,
 - b) between 5 and 60% by weight, relative to the total weight of the composition, of at least one excipient, selected from inert matrices, hydrophilic matrices, lipid matrices, mixtures of inert matrices and of lipid matrices, mixtures of hydrophilic matrices and of inert matrices, with the exception of mixtures comprising a polyacrylic acid and at least one hydrophilic matrix of the cellulose type;
 - c) between 5 and 50% by weight, relative to the total weight of the composition, of at least one alkalinizing agent soluble in an aqueous phase under physiological pH conditions, selected from alkali or alkaline-earth metal hydroxides, carbonates, bicarbonates and phosphates, sodium borate as well as the basic salts of organic acids.
2. Pharmaceutical composition according to Claim 1, characterized in that the active substance is chosen from pseudoephedrine, efletirizine, trapidil and hydrocodone, their optical isomers or their pharmaceutically acceptable salts.
3. Pharmaceutical composition according to either of Claims 1 and 2, characterized in that the matrix excipient is of the hydroxypropyl methylcellulose type.
4. Pharmaceutical composition according to any one of Claims 1 to 3, characterized in that it comprises, in addition, one or more other pharmaceutically acceptable excipients.
5. Pharmaceutical composition according to Claim 3, characterized in that the said one or more other pharmaceutically acceptable excipients is chosen from diluents, binders, disintegrants, lubricants, taste-masking agents, flavourings, colourings or coating agents.

6. Process for preparing a pharmaceutical composition according to any one of Claims 1 to 5, characterized in that it comprises the following successive steps:
 - i. preparation of a homogeneous mixture containing components a, b and c and the other excipients optionally present;
 - ii. tableting of the homogeneous mixture obtained in step i, optionally after granulation.
7. Pharmaceutical composition which can be administered orally, allowing the immediate release of a first active substance and the prolonged release of the same or of a second active substance, comprising
 - A. at least one layer comprising an active substance and excipients which allow immediate release of the said active substance after administration, and
 - B. at least one second layer which allows the controlled release of the same or of a second active substance, this layer being a pharmaceutical composition according to any one of Claims 1 to 5.
8. Pharmaceutical composition according to Claim 7, characterized in that the immediate-release layer A is stuck to the prolonged-release layer B.
9. Process for the preparation of a pharmaceutical composition according to Claim 7, characterized in that it comprises the following successive steps:
 - (1) preparation of separate homogeneous mixtures from the components of layers A and B, and
 - (2) tableting of the mixtures obtained in 1) in a multilayer tableting machine.
10. Process of preparation according to Claim 9, characterized in that the tableting step 2) is preceded by a step of granulating the homogeneous mixtures obtained in step 1).